

REMARKS

Reconsideration and allowance of the pending claims is respectfully requested. Claims 26-50 and 52-75 are pending. Claim 51 has been canceled without prejudice or disclaimer. Claims 26-27, 29, 31, 35, 38-40 and 46-50 have been amended to more clearly recite the subject matter deemed the invention. Support for the amended claims can be found in the claims as filed and throughout the specification. New claims 53-75 have been added. Support for these new claims can be found throughout the specification as filed. Applicants respectfully submit that no new matter has been introduced via these amendments to the claims.

Applicants' agent notes the Examiner's objection to the drawings and format of the specification. Applicant's agent requests that these objections be held in abeyance until the parties reach agreement on patentable claim language, at which time corrected drawings and substitute pages of the specification will be submitted.

The Examiner rejected claims 26-52 under 35 USC §112, first paragraph, suggesting that the disclosure is not enabling for the scope of the subject matter claimed. Applicants respectfully traverse this rejection for at least the following reasons.

Applicants have submitted two declarations by scientists working in the field, further exemplifying the invention. Although the Examiner states at the top of page 2 of the Official Action that he has reviewed the content of the second of these documents, the content of the Declaration of Dr Thomas does not appear to have been taken into account when assessing the disclosure. For instance, the Examiner states that the Applicants have only shown the use

of a malate synthase promoter. Applicants do not agree with this statement. The data presented by Dr Thomas shows that other promoters may be substituted and similar effects are observed. If the Examiner has considered this data, he is requested to state why he has apparently disregarded it, such that Applicants may have an opportunity to respond to his concerns.

In addition, Dr Thomas made reference in point 11 of his Declaration to other disrupter genes which may be substituted for barnase. Again, the Examiner is silent with respect to these statements; an explanation is requested.

Applicants note that the paragraph at the top of page 5 of the Official Action appears to be a reiteration of standardized jargon on the subject of gene silencing, and the like. Dr Jepson addressed the issues pointed out on page 5 fully in his Declaration, filed in connection with an application from which the present application is derived. Applicants request that this Declaration be made of the record for the present case, and that the Examiner respond to the comments made therein.

Applicants respectfully submit that claims are fully supported by the specification as filed, and that the Section 112 (1)-based rejections be withdrawn.

The Examiner rejected claims 25-52 under 35 USC § 112, second paragraph, as being indefinite. The expression "selected stage of plant development" as used in claim 26 and 27 was deemed to be indefinite. This term has been replaced with the term "predetermined".

Likewise, the Examiner objected to the term "desired characteristic" present in claim 26 and elsewhere. The alternatives in claim 27, were objected to as being indefinite.

The Examiner objected to claim 29 for reciting that the disrupter gene encodes a

cytotoxin which disrupts cell function, leading to cell death.

Claim 31 is intended to encompass constructs such as sense or anti-sense RNA constructs which do comprise nucleotide sequences and function by inhibiting translation of a gene. Furthermore, "endogenous plant genes" are, by definition, those found in the plant genome and not those introduced by the construct. If necessary, please clarify the claim language to make these concepts clear or explain them to the Examiner.

An objection was made to the language of claim 35. Applicants amended the claim to recite that the promoter is "normally active only during germination", which clearly eliminates the case argued by the Examiner, stating every promoter active during germination etc. is encompassed by the claim.

The Examiner objected to spelling errors in claims 38 and 46. The objection to the spelling of aleurone in claim 38 has been addressed by correction. Similarly, the spelling of "barnase" in claim 46 has been corrected.

The Examiner objected to the term "inserted gene" in claims 39 and 40. This term has been clarified by amendment.

The Examiner objected to claims 48-50 for reciting the phrase "recombinant genomes". Applicants note that these are genomes which have been altered using recombinant DNA technology. The objection has been addressed by specifying that the relevant claims (48-50) relate to transformed genomes.

The objection to claim 51 is rendered moot via cancellation of this claim.

The objection to claim 52 indicates the Examiner's fails to understand the invention. The plant may be intrinsically unable to grow to maturity, but by using the system of the

invention and applying an exogenous chemical inducer, the inhibitory effect may be overcome. This will therefore allow plants to mature in certain circumstances. The generation of plants which simply do not grow is not useful. However, if one can control the growth, one may effectively contain genetic material.

Applicants respectfully submit that the claims as amended are definite.

The Examiner rejected claims 26-28, 35, 42 and 47-50 under 35 USC § 102(b) as being anticipated by, or in the alternative, under § 103(a) as being obvious over Bridges et al. Applicants traverse this rejection for the following reasons.

The claimed invention is drawn to an expression system which is functional in a plant, the system including an inducible promoter sequence responsive to the presence or absence of an exogenous chemical inducer and either a gene encoding a repressor protein under control of the inducible promoter or a gene encoding an inhibitor of a disrupter gene, the disrupter gene encoding a protein disrupter of a plant characteristic that is either essential for growth or is a desired characteristic resulting from gene insertion, the effect of the system not only acting on the biosynthesis of viable pollen. In not acting only on the biosynthesis of viable pollen and in disrupting another characteristic of a plant, such as a characteristic that is essential for growth, beyond the production of viable pollen, the present invention necessarily acts to prevent or alter the growth or development of established plants or seeds. By the present invention, it is now possible to control volunteers or premature sprouting. The invention as now defined in the claims is clearly not directed to producing otherwise healthy, unaffected plants which are simply unable to produce viable pollen. The present invention, as now claimed, requires that the plant itself, not just the viability of the pollen, is effected by

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the expression system; that is, the plant itself is inhibited, killed or altered as a result of the presence or absence of controlling chemical.

The whole of the specification fully supports the claims. As taught in the specification, it is the discovery of the Applicants, that an expression system can now be provided which is responsive to an exogenous chemical inducer such that the chemical inducer can by its presence or absence cause the expression system to prevent or alter the growth or a characteristic of an established plant, that characteristic not being limited to the production of viable pollen. Such an expression system has not before been described in the prior art.

Applicants note that Bridges is specific for the production of plants which are reversibly male sterile. This is a very specific application, required for hybrid plant production, wherein such production is controlled by the specific disruption of pollen biogenesis. Healthy viable seeds are required from the hybrid seed of Bridges et al. No suggestion is made to direct an artisan to investigate any other form of inhibition. There would have been no motivation to use other promoters as suggested by the Examiner, since there was nothing in the art to motivate the skilled person to consider doing so at the time the invention was made. No other inhibition would be appropriate in view of the target of the process of reversible or controllable male sterility.

Male sterility is not the claimed invention. The claimed invention is directed to methods of preventing or altering growth or development of established plants or seeds. The claimed invention does not require otherwise healthy plants that are simply unable to produce pollen, as is the aim of Bridges et al. Applicants respectfully submit that Bridges et al neither

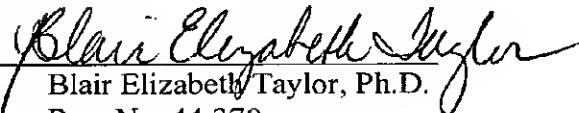
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anticipates nor renders obvious the claimed invention, and that the art-based rejections should be withdrawn.

In view of the above amendments to the claims and the foregoing remarks, the Applicants respectfully assert that all of the Examiner's objections and rejections have been overcome. Accordingly, a favorable notice of allowance of the present application is respectfully requested. Should questions related to patentability remain, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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Enclosure: Appendix

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The claims have been amended as indicated below.

26. An expression system functional in a plant comprising:

(a) an inducible promoter sequence responsive to the presence or absence of an exogenous chemical inducer;

(b) either

(i) a gene encoding a repressor protein under control of said inducible promoter; or

(ii) a gene encoding an inhibitor of the disrupter gene specified at (d) below under control of said inducible promoter;

(c) a plant developmental gene promoter sequence activated at a [selected] predetermined stage of plant development, which, in the case of (b)(i) above, includes an operator sequence recognized by said repressor protein, the presence of which inactivates said plant developmental gene promoter;

(d) a gene encoding a protein-disrupter of a plant-characteristic, wherein said plant characteristic is either essential to plant growth or is a [desired] characteristic resulting from gene insertion, under the control of said plant developmental gene promoter sequence; wherein the presence or absence of the exogenous chemical inducer controls whether said characteristic is displayed in the plant,

wherein said system does not act only to disrupt the biosynthesis of viable pollen.

27. An expression system as claimed in claim 26 where the plant characteristic controlled by the system is essential to plant growth, whereby the presence or absence of the exogenous chemical inducer [allows either] induces a response selected from the group consisting of growth to maturity [or causes] retarded growth [to slow down or stop] and growth cessation at said [selected] predetermined stage.

29. An expression system as claimed in claim 26, wherein the expression system comprises a disrupter gene [encodes] encoding a cytotoxin which disrupts cell function, leading to cell death.

31. An expression system as claimed in any one of claims 26 or 27, wherein the disrupter gene encodes [a nucleotide] an RNA sequence [adapted to inhibit] that inhibits an endogenous plant gene [which is] essential to plant development, or an inserted gene conferring a [desired] predetermined characteristic on the plant.

32. An expression system as claimed in claim 31, wherein said nucleotide sequence is in antisense orientation to the gene to be inhibited and corresponds to less than the full length of said gene to be inhibited.

33. An expression system as claimed in claim 31 in which the gene to be inhibited is an endogenous plant gene essential to seed germination or early seedling development.

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35. An expression system as claimed in claim 26 in which said plant development promoter sequence is the promoter of a gene normally active only during germination or early seedling development.

38. An expression system as claimed in claim 35, wherein said promoter is selected from the group consisting of the gene promoters of glyoxysomal enzyme genes, [aleutrone] aleurone layer genes and carboxypeptidase genes.

39. An expression system as claimed in claim 30, in which the recombinase gene is the FLP gene of the 2 micron plasmid of *Saccharomyces cerevisiae* and the recognition sequences are the FRT sequences which flank all or part of an inserted gene or its regulatory elements, wherein the inserted gene is a gene encoding a predetermined characteristic introduced into the plant by a recombinant DNA method.

40. An expression system as claimed in claim 30, wherein the recombinase gene is the Cre gene of bacteriophage P1 and its recognition sequence or the lox sequences which flank all or part of an inserted gene or its regulatory elements, wherein the inserted gene is a gene encoding a predetermined characteristic introduced into the plant by a recombinant DNA method.

46. An expression system as claimed in claim 26, wherein the disrupter gene encodes

[bamase] barnase and the gene encoding the inhibitor of the disrupter gene contains the coding region of the barstar gene which on expression produces a protein inhibitor of barnase.

47. A [recombinant] plant genome [comprising] transformed via an expression system as claimed in claim 26.

48. A plant having a [recombinant] transformed genome as claimed in claim 47.

49. A plant part having a [recombinant] transformed genome as claimed in claim 47.

50. A plant cell having a [recombinant] transformed genome as claimed in claim 47.